

App. No. 10/065,898

REMARKS - General

By the above amendment, Applicants have amended the title to emphasize the novelty of the invention.

Background:

Vaginitis is characterized by signs of vulvovaginal inflammatory objective changes, such as redness, edema, fissures, excoriation, ulceration and discharge, and subjective vulvovaginal symptoms, such as itching, burning, and discomfort.

Vaginitis is the most common gynecologic diagnosis in the primary care setting. In 90% of affected women, this condition occurs secondary to bacterial vaginosis, vulvovaginal candidiasis or trichomoniasis (Sobel 1997 and 1999). Non-infectious causes include atrophic vaginitis, allergic reactions and chemical irritation. Among women of childbearing potential, bacterial vaginosis is currently the most common cause of vaginitis, accounting for 40 to 50% of cases in the US (Hill 1993). Vulvovaginal vaginitis is the second most frequent cause of vaginitis in the United States, and most common cause in Europe (Kent 1991). Acute common vulvovaginal candidiasis accounts for 13 million cases yearly in the United States (Horowitz 1992) and is a common and increasing reason for visiting the gynecologist (Dun 2000). An estimated 75 percent of women acquire vaginal candidiasis at some time in life, and 5 percent of women have recurrent infections. *Candida albicans* is the infecting agent in 75 to 90 percent of patients, with recent increases of non-*albicans* species (*candida glabrata* and *krusei*), possibly related to greater use of antifungal OTC products. Of note, about 20 to 30 percent of women have asymptomatic yeast colonization detected incidentally on Pap smears, and do not require treatment (Coco 2000, Jovanovic 1991).

The etiology of vaginitis can be established by microscopic examination of wet-mount and KOH preparations of vaginal discharge. If the etiology of vaginitis cannot be determined by these standard tests, additional confirmatory tests may be performed. Microscopic examination of wet-mount by an experienced examiner including the search for "clue cells", yields a sensitivity of 60 percent and a specificity of 98 percent in diagnosing bacterial vaginosis (Egan 2000). Examination of vaginal discharge

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in a 10 percent KOH solution is useful in detecting candidal hyphae, mycelial tangles and spores, and is positive in 50 to 70 percent of women with vaginal yeast infections (Sonnex 1999).

Said composition is an additive to a comfortably warm sitz bath, which has been developed for symptomatic relief of feminine itching. Antibiotic and antifungal treatment will generally become effective in alleviating the symptoms of vaginitis after 2 to 7 days of treatment. Until the effect of antimicrobial treatment sets in, patients often have to suffer from irritating and tormenting vaginal symptoms. The active homeopathic ingredients of the composition are listed in the Homeopathic Pharmacopoeia for indications including urogenital disease, leukorrhea, pruritus vulvae and inflammation of mucous membranes. A majority of the patients report relief of vaginitis symptoms, and at the same time it is well tolerated and not associated with any adverse reactions. Regarding the safety, no relevant side effects are expected from the homeopathic ingredients, which are all delivered in a 30X potency. From a chemical perspective, 30X potencies are diluted beyond material action ($1:10^{-30}$) and do not contain any molecules or substances of toxic potential.

Alternative medications for symptomatic treatment of vaginal itching are antihistamines and local anesthetic creams. Intake of antihistamines is frequently associated with drowsiness, and local application of vaginal creams is not a popular therapeutic intervention with many women. Vaginal itching is the most prominent clinical symptom of vaginitis.

Identification of patients in need of said composition:

Diagnosis of vaginitis established by the following criteria;

Vulvovaginal inflammatory objective changes, such as redness, edema, fissures, excoriation, ulceration and discharge, and subjective vulvovaginal symptoms, such as itching, burning, and discomfort.

Mild, moderate or severe vaginal itching. Positive laboratory tests like KOH, wet mount or cultures.

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Measurement of potency:

The Pharmaceutical manufacture of most homeopathic medicines begin by creating the "Mother Tincture" from the natural base substance. The Mother Tincture is then diluted according to the decimal (X) scale. Between each dilution level it goes through Potentization.

In Homeopathy, the higher the dilution level, the more deeply the remedy acts. Homeopathic medicine are micro-dosed natural substances derived from botanical, animal or mineral sources. A specific homeopathic medicine dilution is obtained by a precise and controlled process of successive "homeopathic dilution". The medicine is diluted or de-concentrated and then vigorously shaken, traditionally referred to as succussion. This process transforms the original substance into a therapeutically active medicine.

Homeopathic medicine potency in the U.S.A. is described by a two part, number and letter designation (30X for example). The number part indicates the number of times the source substance has been homeopathically diluted. The Letter portion indicates the dilution rate. X being the roman numeral 10, is the slowest dilution rate of 1/10 and LM is the fastest dilution rate of 1/50,000.

Clarification of component:

(Please refer to the attached document for detailed description of homeopathic ingredients). The combination of homeopathic components with other disclosed ingredients of the invention provide the desired therapeutic effect.

Claim 22:

Kang et al (US Patent 5,098,709) and Levin et al (US Patent 6,027,716 have a different combination in and application functionality than our composition therefore claim 22 should not be rejected.

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Conclusion

For all of the above reasons, applicant submits that the specification and claims are now in proper form, and that the claims all define patentably over prior art. Therefore the applicant submits that this application is now in condition for allowance, which action is respectfully solicited.


Respectfully submitted,



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I hereby certify I have transmitted this paper by fax to the Patent and Trademark Office at 571-273-8300 on July 29, 2005

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